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NEWS AND VIEWS

Genetic Databases: Assessing the Benefits and the Impact on Human and Patient Rights – a WHO report

GRAEME LAURIE*

This article summarises the underlying rational and provisions of a report on genetic databases prepared for the European Partnership on Patients' Rights and Citizens' Empowerment, a network of the World Health Organisation Regional Office for Europe. The Working Group that prepared the report consisted of Fons Dekkers,¹ Alastair Kent,² Graeme Laurie (Convener),³ and Carmel Shalev.⁴ The report is available at: <http://www.law.ed.ac.uk/ahrb/publications/online/whofinalreport.pdf>.

The recommendations of the report are set against the existing international human rights framework, from which the following guiding values are extracted:

- The pursuit of human well-being
- The quality of human dignity, including the principle of non-discrimination
- The principle of respect for persons, including the imperatives of beneficence, non-maleficence, and respect for individual autonomy.

The report examines the ethical, social and legal issues that surround the creation and operation of databases containing human genetic material. It is important to note, however, that genetic influences rarely determine an individual's health status, and they never determine what it means to be an individual. It is, therefore, imperative that we do not place too much emphasis on genetics in discussing the human condition. We are, each of us, more than the sum of our genetic component parts.

Moreover, we cannot easily distinguish between genetic information and medical information more generally; it is important therefore also to set any analysis of genetic databases in the wider context of health databases. This is not to deny, however, that certain elements of certain forms of genetic information throw up particular problems. Monogenic disorders are a clear example because

of the relatively high predictability of disease in relatives. In such circumstances, the argument can be put that the information belongs to the family and not simply to the individual who has been tested. If this is accepted, however, it raises the problem of how to resolve conflicts over use or non-use of the information.

The recognition of the familial, and at times communal, quality of many forms of genetic information led to the conclusion that rigid adherence to an individualistic, autonomy-driven perspective would not be appropriate for the tenor of the report. The role of the public interest came in for close scrutiny in tandem with the examination of individual rights. In most circumstances, therefore, a balance of legitimate interests was sought.

Key recommendations

There follows a brief account of the central recommendations made in the report.

- 1) Individuals are entitled to control the use of their samples and information, in a manner akin to a property right. This right may, however, be subject to waiver or certain limits, such as when anonymisation occurs or when certain uses may cause harm to others.
- 2) Collection of genetic data should normally be allowed only for the purpose of promoting public health. The onus is on those who would seek to use data outside this purpose to justify doing so.
- 3) The onus will be on those who seek to create the database to justify its nature, purposes, content and uses. In particular the following factors must be satisfactorily established:
 - i) The public interest that will be furthered by the creation of the database;
 - ii) The relevance of genetic data to the purposes of the database;
 - iii) That the creators of the database are able to restrict the use of the data to the purposes for which it was sought;
 - iv) That the creators of the database are able to ensure adequate security measures for the data and for privacy protection;
 - v) That the creators and users of the database have sufficient competence to understand the data;
 - vi) That the creators and users of the database have the ability to understand the context in which the information comes, and the relevance of other factors which further contextualise the information.

- vii) That the creators have considered ethical aspects and made appropriate provisions to respect human rights.
- 4) An appropriate ethical approval mechanism should be established to oversee the creation and maintenance of genetic databases. Any appointed body should assume a range of detailed duties which are laid out in the report, including, the consideration of ethical questions concerning the use of the database, and the data contained therein and the production of codes of conduct governing the establishment and maintenance of genetic databases.
 - 5) Public debate should precede the establishment of new genetic databases. No database should be established if public trust is seriously in doubt.
 - 6) When obtaining consent to the provision of a sample or information for a genetic database, participants should be informed to the following extent:
 - i) Participants should be given sufficient information to make a meaningful choice about participation, including information about the purposes of the database and its commercial potential;
 - ii) Sufficient information should be provided to ensure that participants comprehend the nature of the enterprise to their own satisfaction;
 - iii) Participants should be given the opportunity to ask questions and have these answered;
 - iv) Participants should be informed of the risks of participating, where these exist;
 - v) Participants should be informed of the security provisions that exist to protect their personal data;
 - vi) Participants should be informed of the alternatives to participating, and in particular, should receive assurances that no adverse consequences will follow if they choose not to participate;
 - vii) Participants should be informed of the uses to which data might be put;
 - viii) Participants should be informed of the possibility of future uses of data, beyond the limits of the present consent, and should be provided with an opportunity to withhold consent to such uses.

Developments since this report indicate that these recommendations may not be appropriate in all cases. For example, the UK Biobank project is designed to collect samples and information from 500,000 UK citizens aged between 45 and 69 and to scrutinise participants' records towards and beyond death.⁵ The aim is to explore the relationship between genetics and other factors in the onset of disease. The long-term nature of the endeavour means

that prospective uses cannot be foreseen and so cannot form part of the original consent and re-consenting will not be practicable. Open-ended consent is therefore proposed. This prospect is, nonetheless, covered by a further recommendation in the report that:

- 7) Blanket future consent is permissible where anonymity can be guaranteed, and there is no risk that unexpected results will filter back to the subjects concerned. If this guarantee is not possible, or if linking of data is necessary for the research, then specific consent to the research must be obtained.
- 8) For vulnerable adults all current international guidelines should be complied with. Children are also considered as a separate category. In both cases, contributions to a database are possible within stringent safeguards.
- 9) Research using archival material – for which no specific consent has been obtained – is permissible if the material and information derived from it is anonymised, and there is no prospect that research results will be used to identify the sample sources at any future time.
- 10) The anonymisation process should be overseen by an independent body with attendant duties explained in the report.
- 11) Feedback to participants should not normally be provided from genetic research data. This principle should be departed from only with ethical approval and if:
 - i) the data have been instrumental in identifying a clear clinical benefit to identifiable individuals;
 - ii) the disclosure of the data to the relevant individuals will avert or minimise significant harm to those individuals;
 - iii) there is no indication that the individuals in question would prefer not to know.
- 12) Adequate account must be taken of the privacy interest that individuals have in *not* knowing information about themselves.⁶
- 13) Those who would seek to depart from the practice of requiring active informed consent prior to participation in the creation of a genetic database must justify this position in strong ethical terms. As a minimum the following criteria must be satisfied: (a) a clear, realisable and significant public health benefit must be identified, (b) the widest possible educational programme must be instituted among the population that will participate, including an

opportunity for public debate (c) strong privacy protection measures must be implemented, (d) individuals must at all times be given the opportunity to refuse to participate, and (e) every stage of the process must be subject to the most stringent ethical scrutiny.

- 14) The gathering and storage of genetic samples and information must be subject to rigorous privacy protection measures in conformity with international and national data protection laws. These privacy measures must be transparent and subject to ethical approval by a suitable body.
- 15) It should be the role of an independent body to oversee and regulate access to genetic databases. This same body should hold the key(s) to any anonymisation methods. The body should receive applications for access for consideration in light of the nature and purposes of the database. The body must be satisfied that the party seeking access is able to make responsible use of the data and to respect their status. The use of finite resources such as genetic samples must equally be regulated by ethically appropriate means.
- 16) Every participant has the absolute right to withdraw at any time and without reason. All information and samples should be destroyed on request unless it can be shown that it is not reasonably practicable to do so.
- 17) Serious thought should be given to the role of property rights for individuals in their own samples and benefit sharing to participant communities as a means to foster and maintain public trust and confidence in genetic databases.
- 18) The establishment, maintenance and operation of genetic databases should be carried out in an atmosphere of openness, transparency and appropriate ethical scrutiny. Accountability of database creators, managers and users should be given. Consideration should be made of the ways in which this can be achieved, including legal measures to regulate and control the creation and management of databases, and duties to report publicly on activities in respect of the database.

Notes:

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5. <http://www.ukbiobank.ac.uk>
6. For further discussion see GT Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms*, Cambridge, Cambridge University Press, 2002.